UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

PHARMATHEN, S.A., Plaintiff, *-against-* LACHMAN CONSULTANT SERVICES, INC., Defendant.	Case No. **COMPLAINT FOR (1) BREACH OF CONTRACT; (2) GROSS NEGLIGENCE; (3) NEGLIGENT PERFORMANCE OF SERVICES** **JURY TRIAL DEMANDED**

Plaintiff Pharmathen, S.A. ("Pharmathen"), by and through its undersigned counsel, for its Complaint against Defendant Lachman Consultant Services, Inc. ("Lachman"), alleges and states as follows:

NATURE OF THE ACTION

1. This action arises out of Lachman's failure to timely file Pharmathen's Abbreviated New Drug Application ("ANDA") on March 27, 2017 seeking U.S. Food and Drug Administration ("FDA") approval to manufacture and market a generic version of the drug known as Tecfidera®. Lachman's failure in this regard caused Pharmathen to forever forfeit its right to achieve critical "first-filer" status for its ANDA under the Hatch-Waxman Act, and precluded Pharmathen from obtaining potential marketing exclusivity rights for a generic version of Tecfidera® and the revenue streams those first-to-file rights bring to generic pharmaceutical companies who achieve the critical "first-filer" status.

2. Pharmathen is a pharmaceutical company engaged in, *inter alia*, the manufacture and marketing of generic versions of brand name drugs. Lachman is a consulting firm that specializes in assisting pharmaceutical companies like Pharmathen in obtaining approval from the FDA to manufacture and market generic drugs in the United States.

3. Pharmathen retained Lachman as a consultant and as its agent to perform services in connection with Pharmathen's filing of an ANDA with the FDA for approval to manufacture and market dimethyl fumarate as a generic version of Tecfidera®.

4. Pursuant to a Consulting Agreement dated January 23, 2017 (the "Consulting Agreement") and related documents and communications, Lachman agreed to submit Pharmathen's ANDA for dimethyl fumarate (the generic version of Tecfidera®) on March 27, 2017 – the one and only day in which a company can secure eligibility for certain generic drug exclusivity rights under the Hatch-Waxman Act as a first-filer, as described in further detail herein. Through addendums to the Consulting Agreement, Lachman further affirmatively agreed to act as Pharmathen's agent for purposes of timely submitting Pharmathen's ANDA to the FDA, i.e., on March 27, 2017.

5. Tecfidera®, a drug directed toward the treatment of relapsing multiple sclerosis, was FDA approved and made commercially available in the United States in 2013. Since that time, Pharmathen has invested substantial time and resources investigating the potential for manufacturing and marketing a generic version of the drug. Among other things, Pharmathen has invested substantial research and development resources into analyzing the nature of the drug including its formulation and active compound, the resources necessary to develop and manufacture a generic version of the drug, conducting economic and marketing analyses of selling a generic version of Tecfidera®, and evaluating patents that purportedly cover the drug compound and methods of using the same.

6. After serious evaluation and consideration of all of the factors outlined above, Pharmathen made a decision to proceed with developing a generic version of Tecfidera®. Pharmathen knew that in order to market its generic version of Tecfidera® in the United States, Pharmathen needed approval from the FDA. Pharmathen is based in Greece, and had never

before filed an ANDA with the FDA in its own name. Pharmathen accordingly sought out an experienced consulting firm who claimed to have the expertise, capability and experience to assist Pharmathen with the preparation and submission of its ANDA for dimethyl fumarate. Lachman, which holds itself out as setting "the industry standard" for such services, assured Pharmathen that it could perform the services Pharmathen needed. Specifically, Lachman assured Pharmathen that it would (1) assist Pharmathen in preparing the ANDA in the form and with the content required by the FDA, and (2) file the ANDA with the FDA on the critical date of March 27, 2017.

7. Despite assuring Pharmathen that Pharmathen had provided all of the information required for Lachman to timely file the ANDA, and despite representing to Pharmathen time and again that the ANDA would be filed on March 27, 2017, Lachman inexplicably failed to do so. Lachman filed Pharmathen's ANDA for dimethyl fumarate on March 28, 2017, rather than March 27, 2017, with full knowledge that March 27, 2017 was the steadfast and critical filing deadline. Lachman's failure to timely file Pharmathen's ANDA caused Pharmathen to forfeit potential generic drug marketing exclusivity rights it could have been eligible for but for Lachman's failure to fulfill its contractual obligations, duties, and professional responsibilities to Pharmathen as Pharmathen's consultant and agent. Lachman's failure to file the ANDA by the required deadline is incurable, and Pharmathen has forever lost its potential first-to-file marketing exclusivity rights for a generic version of Tecfidera® as a result of Lachman's gross dereliction of its contractual, agency and professional obligations and responsibilities.

8. By failing to timely file the Pharmathen ANDA, Lachman breached the parties' Consulting Agreement, acted with gross negligence and reckless indifference to and/or disregard of its responsibilities and obligations and Pharmathen's rights, and breached the professional duty of care Lachman owed to Pharmathen by virtue of the parties' relationship. As set forth

herein, Lachman's conduct has caused Pharmathen significant damage including (1) the amounts Pharmathen paid to Lachman under the Consulting Agreement; (2) the revenues Pharmathen would likely have earned had Lachman timely filed Pharmathen's ANDA for dimethyl fumarate as required; and (3) research and development costs and legal fees incurred by Pharmathen, including costs and fees associated with the preparation and evaluation of a generic version of Tecfidera® including the preparation of Pharmathen's ANDA for dimethyl fumarate.

THE PARTIES

9. Pharmathen is a Greek pharmaceutical company focused on the development and marketing of pharmaceuticals with a strong position in generics, and a mission of providing affordable pharmaceutical products to patients in need worldwide. Pharmathen launched its first drug product in 2002, in the European Union, and entered the United States pharmaceutical market in 2013. Pharmathen maintains three state-of-the-art research laboratories and two manufacturing facilities, and employs more than 900 people who work in research, development, production and distribution of drugs to more than 80 countries worldwide. Pharmathen's products are approved in all European Union markets and distributed through the largest pharmaceutical companies in the world, including those situated in the United States.

10. Pharmathen is one of the fastest growing generic drug companies in Europe and has been widely recognized for its achievements. In 2008, Pharmathen received the Greek Entrepreneur of the Year Award from Ernst & Young. In 2010, Pharmathen received the KOUROS Award for Performance in the International Economic Arena. In 2011, Pharmathen was recognized for Research and Innovation by the Athens Chamber of Commerce & Industry. In 2012, Pharmathen was recognized as one of the 50 largest and most profitable companies in Greece by ICAP, and one of the 100 largest Greek industries by Stat Bank. In 2013, Pharmathen received the Ruban d'Honneur "International Growth Strategy of the Year" Award.

11. Upon information and belief, Lachman is a consulting company based in New York. Upon information and belief, Lachman's principal business is in assisting pharmaceutical companies, such as Pharmathen, with FDA filings to secure approval to manufacture and market drugs in the United States. According to its website, since 1978 Lachman has maintained a team of highly experienced FDA and industry experts through which Lachman has offered compliance, regulatory affairs, and technical services to pharmaceutical clients around the world.

12. In the specific area of FDA-related services, and according to Lachman's website, Lachman offers the following services:

> Lachman Consultants offers FDA-related services to clients, such as document preparation/reviews, audits and reviews, compliance problem resolution, training, regulatory affairs strategic assistance, preparation and/or review of regulatory filings, and other special services.

13. According to Lachman's website, Lachman's expertise includes "[p]repar[ing] and submitt[ing] ANDAs and NDAs (including eCTDs)," and "[f]acilitat[ing] the timely approval of ANDAs and NDAs, including first-time generic approvals." The electrical common technical document (eCTD) is an electronic format used by the pharmaceutical industry to submit or transfer information to the FDA.

14. Upon information and belief, Lachman purports to have "a well-earned reputation for helping to ensure that documents submitted to the FDA are of the utmost quality—helping to accelerate positive outcomes." Upon information and belief, Lachman purports to have assisted hundreds of domestic and international clients in reviewing and preparing key documents for review by the FDA, including ANDAs. Upon information and belief, Lachman holds itself out as providing "The Pharmaceutical Experience and Reputation You Can Trust," and boasts that it maintains a staff of "highly experienced consultants who consistently deliver top quality results."

JURISDICTION AND VENUE

15. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(a)(2) because Pharmathen is a Greek corporation with its principal place of business in Athens, Greece, and Lachman is a New York corporation with its principal place of business in Westbury, New York, and the amount in controversy exceeds $75,000.

16. Venue properly lies in the Southern District of New York because the Consulting Agreement executed by the parties provides that any action or suit arising thereunder shall be subject to the exclusive jurisdiction of the federal or state courts located in the County of New York, State of New York. Venue is also proper pursuant to 28 U.S.C. § 1391(b)(1).

FACTUAL BACKGROUND

The Hatch-Waxman Act

17. The Hatch-Waxman Act, codified at 21 U.S.C. § 355, *et seq.*, governs the FDA regulatory approval process for generic prescription drugs. Its purpose is to "strike a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed Cir. 2002).

18. A brand pharmaceutical company who wishes to market new, previously unapproved drugs must obtain approval to do so from the FDA by filing a New Drug Application ("NDA"). *See* 21 U.S.C. § 355 (a), (b). In addition to providing the FDA with a multitude of testing, efficacy and safety information regarding the drug that is the subject of the NDA, the brand pharmaceutical company must also provide the FDA with information regarding "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or

sale of the drug." 21 U.S.C. § 355(b)(1). Upon receipt of that information, the FDA lists the patents identified for the approved NDA in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly known as the "Orange Book." 21 U.S.C. § 355(j)(2)(A)(i).

19. New drugs approved on the basis of safety and effectiveness by the FDA are known as "listed drugs" because they are listed in the FDA's Orange Book along with any of the patents identified by the NDA holder that purportedly cover the drug. The Hatch-Waxman Act provides for an expedited approval process for generic versions of listed drugs through an ANDA. 21 U.S.C. § 355(j). Under the ANDA process, generic pharmaceutical companies seeking to manufacture a generic version of a listed drug can rely on the research of the brand pharmaceutical company to establish the safety and efficacy of the generic version, as long as the generic pharmaceutical company demonstrates, *inter alia*, that its generic drug product is "bioequivalent" to the listed drug. 21 U.S.C. § 355(j)(2)(A)(iv).

20. To establish that its proposed generic drug product is bioequivalent to the referenced listed drug, a generic pharmaceutical company must submit data from testing that shows to the FDA's satisfaction "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives become available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1(e).

21. In addition, as part of its ANDA, a generic pharmaceutical company must submit one of four certifications with respect to each patent listed in the Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii). In one such certification, known as a Paragraph IV Certification, the generic pharmaceutical company certifies that in its opinion, the one or more of the patents listed in the

Orange Book as covering the drug for which it seeks FDA approval to market a generic version of is invalid and/or will not be infringed by the manufacture, use or sale of the generic drug. *Id.*

22. The timing of a generic pharmaceutical company's filing of an ANDA to obtain approval from the FDA to manufacture a generic version of an Orange Book-listed drug is critical. The first generic company (or companies) to file an ANDA with a Paragraph IV Certification on one or more patents listed in the Orange Book that purportedly cover the listed drug is eligible to receive a period of generic exclusivity in which it can market its generic version of the listed drug free from any other generic competition once the ANDA is approved by the FDA. Specifically, and subject to certain forfeiture provisions, the Hatch-Waxman Act grants the "first-filer" of a Paragraph IV Certification a 180-day period of generic marketing exclusivity during which time the FDA will not approve a subsequently-filed ANDA based on the same listed drug. 21 U.S.C. § 355(j)(5)(B)(iv). In other words, the Hatch-Waxman Act provides a generic pharmaceutical company that is the first to submit a Paragraph IV Certification with its ANDA a potential significant market advantage over subsequent ANDA-filers via market exclusivity.

23. The earliest date upon which a generic pharmaceutical company may file an ANDA depends upon whether the listed drug that is the subject of the NDA upon which the ANDA is based is subject to "New Chemical Entity" regulatory exclusivity. A New Chemical Entity is "a drug that contains no active moiety that has been approved by the FDA in any other application submitted under section 505(b) of the Act." 21 C.F.R. § 314.108(a). If the ANDA applicant seeks approval to manufacture and market a generic version of an Orange Book-listed drug that *is not* a New Chemical Entity, the ANDA can be submitted to the FDA at any time.

24. If the ANDA applicant seeks approval to manufacture and market a generic version of an Orange Book-listed drug that *is* a New Chemical Entity, however, different rules

apply. The holder of an approved NDA for a listed drug that is a New Chemical Entity is entitled to a period of regulatory exclusivity during which time an ANDA seeking approval for a generic version of the listed drug may not be filed or approved. Specifically, the period of exclusivity during which the ANDA cannot be filed or approved extends five years from the date the NDA was approved. 21 C.F.R. § 314.108(b)(2). The exception is that an ANDA that contains a Paragraph IV certification of patent invalidity or non-infringement with respect to one or more patents listed in the Orange Book can be filed although not approved prior to the expiration of the five year period. Specifically, a pharmaceutical company that wishes to file an ANDA containing a Paragraph IV certification as early as possible to obtain the coveted "first-filer" status can do so four years after the NDA for the New Chemical Entity was approved. This is because the FDA is barred from accepting for filing any ANDA containing a Paragraph IV Certification to a listed patent until four years into the five year exclusivity period. *See* 21 C.F.R. § 314.108. In industry parlance, this is known as the "NCE-1" date, *i.e.*, the date that is one year prior to the expiration of the exclusivity period for the New Chemical Entity.

25. The NCE-1 date is critical for any generic pharmaceutical company who wishes to be an ANDA "first-filer" on an NDA that is subject to New Chemical Entity exclusivity. This is because with New Chemical Entities, all generic pharmaceutical companies are in a position to know when they must file their ANDA to be a "first-filer" and thus eligible to obtain the coveted 180 days of generic marketing exclusivity. Moreover, drugs that are the subject of New Chemical Entity exclusivities typically garner substantial sales in the market, which translates to substantial profits for a generic pharmaceutical company that is able to market a generic version of the drug.

26. Generic pharmaceutical companies like Pharmathen closely monitor NDAs that have been approved for New Chemical Entities and their associated NCE-1 dates, to ensure that

they are in a position to obtain a "first-filer" Paragraph IV Certification status by filing an ANDA with that certification on the first possible date – the NCE-1 date – if they wish to manufacture and market a generic version of the listed drug. Upon information and belief, it is not uncommon for several generic pharmaceutical companies to file an ANDA with a Paragraph IV Certification on the NCE-1 date for a listed drug. Each company that successfully files its ANDA on that date is eligible to be a "first-filer" within the meaning of the Hatch-Waxman Act, and is entitled to eligibility for the 180-day generic marketing exclusivity period provided thereunder, with the exclusivity period being shared among all who successfully file on the first possible date and receive approval of their ANDA from the FDA.

27. In the circumstances described above, a generic pharmaceutical company who files its ANDA with a Paragraph IV Certification *after* the NCE-1 date does not, and cannot, qualify for "first-filer" status or the 180-day marketing exclusivity period that goes along with it. The late-filing pharmaceutical company is a "subsequent or second filer" that is at an extreme disadvantage compared to its competitors who are eligible to market and sell their generic versions of the listed drug that is subject to New Chemical Entity exclusivity for a full 180 days before the late-filer is even able to garner FDA approval for its ANDA and enter the market.

28. A generic pharmaceutical company that arrives late to the game, *i.e.*, one who files its ANDA to manufacture and market a generic version of a listed drug *after* one or more other generic pharmaceutical company has already done so within the strictures of the Hatch-Waxman Act, faces an uphill challenge competing in the generic market. This is because those who achieve a Paragraph IV Certification first-filer status have the distinct advantage of establishing and locking in exclusive contractual relationships with the limited class of suppliers who are authorized to distribute generic versions of listed drugs in the United States.

Tecfidera® (Dimethyl Fumarate)

29. Tecfidera® is a drug directed toward the treatment of relapsing multiple sclerosis and is ordinarily taken in capsule form in varying dosages. The active pharmaceutical ingredient in Tecfidera® is dimethyl fumarate. According to the Orange Book, Biogen IDEC holds the approved NDA for Tecfidera®. Upon information and belief, Biogen IDEC first marketed Tecfidera® in 2013 and quickly achieved significant sales in the pharmaceutical market. Upon information and belief, in 2014 The Boston Globe reported that Biogen IDEC's launch of Tecfidera® was "one of the most successful drug launches in US history." Upon information and belief, Biogen IDEC reported that as of 2015, Tecfidera® was the most prescribed oral multiple sclerosis therapy globally. Upon information and belief, Biogen IDEC reported $946 million in sales of Tecfidera® in the first quarter of 2016, and $987 million in sales of Tecfidera® in the second quarter of 2016. Upon information and belief, Biogen IDEC reported sales of Tecfidera® in excess of $1 billion in each of the third and fourth quarters of 2016. Upon information and belief, independent analysts have forecasted $3.78 billion in sales of Tecfidera® in 2018, and $5.56 billion in sales of Tecfidera® by 2020.

30. Tecfidera® is listed in the Orange Book as subject to New Chemical Entity regulatory exclusivity. The Orange Book lists seven patents that purportedly cover Tecfidera®. According to the Orange Book, the NDA for Tecfidera® was approved on March 27, 2013, and has an NCE exclusivity expiration date of March 27, 2018. As such, the earliest date (NCE-1 date) that a pharmaceutical company could file an ANDA with a Paragraph IV Certification seeking FDA approval to manufacture a generic version of Tecfidera® was March 27, 2017.

The Consultancy and Agency Agreements between Pharmathen and Lachman

31. On December 14, 2016, Lachman submitted a Proposal for Preparation of an ANDA[1] in eCTD Format and United States Agent Services to Pharmathen on December 14, 2016 (the "ANDA Proposal"). In the ANDA Proposal, Lachman agreed to provide, *inter alia*, "regulatory support for pre-ANDA communications with the FDA, preparation, publication, and submission of the ANDA, and United States Agent Services," "conduct an ANDA filing review of the documents provided by Pharmathen" and provide written comments to Pharmathen "[w]here deficiencies are noted." Lachman further agreed to "prepare and complete the eCTD, publish, and submit the ANDA to the FDA through the Electronic Submissions Gateway."

32. On January 23, 2017, Pharmathen and Lachman executed a Consulting Agreement, through which Lachman agreed to provide certain consulting services to Pharmathen. The ANDA Proposal was annexed to and made part of the Consulting Agreement. The preamble of the Consulting Agreement states that the consulting services to be provided by Lachman to Pharmathen include those related to ANDA filing procedures. Section 1.1 of the Consulting Agreement provides:

> LACHMAN undertakes to provide the services in accordance with proposals for projects, either annexed as exhibits to this Agreement or thereafter which are signed by both parties. Any such proposals will be a part of this Agreement and consist as an integral part of it. *LACHMAN shall use reasonable skill and care in the performance of the services on the basis of schedules, expectations, methodologies, reports, resources and time frames set forth in the relevant proposals for each project as mutually agreed to by PHARMATHEN and LACHMAN.*

33. In its cover letter to the ANDA Proposal, Lachman recognized and acknowledged that Pharmathen had not previously filed an ANDA: "*[F]or first time ANDA applicants,*

---

[1] Capitalized terms used herein are defined in the Consulting Agreement, and emphasis supplied herein is Plaintiff's, unless otherwise indicated.

additional consulting times in the range of 40-200 hours have *been encountered over and above the general ANDA estimate* due to the extensive interactions required between [Lachman] and the applicant to obtain the required information."

34. On January 23, 2017, the parties executed a US Regulatory Agent Addendum to the Consulting Agreement (the "Regulatory Agent Addendum"). Under the Regulatory Agent Addendum, Lachman agreed to "serve as the United States Regulatory Agent . . . . for Pharmathen," and assumed certain enumerated responsibilities, including the responsibility to "[s]ubmit finalized eCTD applications . . . based on information prepared or provided by Pharmathen, to the FDA through the Electronic Submissions Gateway, as requested." Lachman further agreed that "all future regulatory submissions will be submitted by and under the letterhead of Lachman, with or without corresponding covering document under letterhead of Pharmathen . . . ." Lachman further agreed to "[c]ountersign, solely as Agent, FDA forms, as required."

35. Within the Regulatory Agent Addendum, Lachman identified Lachman Principal Consultant Terri Nataline as the "primary contact person at Lachman in the Agent capacity on behalf of Pharmathen." Upon information and belief, Ms. Nataline is an attorney who was admitted to the New York State Bar in 2001. Upon information and belief, prior to her employment as in-house counsel with Lachman, Ms. Nataline was an attorney in private practice for several years with a focus on litigation between brand pharmaceutical companies and generic pharmaceutical companies arising from ANDAs filed by generic pharmaceutical companies. Upon information and belief, Ms. Nataline has consequently been aware at all relevant times of the procedural intricacies of ANDA submissions, including the critical importance of filing an ANDA based on a New Chemical Entity on the NCE-1 date in order to be eligible to obtain the 180-days of generic marketing exclusivity provided under the Hatch-Waxman Act.

36. The parties agreed that pursuant to the parties' ANDA Proposal and the Consulting Agreement (inclusive of the Regulatory Agent Addendum), Lachman would file Pharmathen's ANDA for dimethyl fumarate with the FDA on March 27, 2017 -- the NCE-1 date applicable to an ANDA with a Paragraph IV Certification seeking the benefit of the NDA approved for Tecfidera®.

Lachman's Failure to Timely Submit Pharmathen's ANDA for Dimethyl Fumarate

37. Pharmathen made it clear to Lachman early on in the parties' engagement that that March 27, 2017 was the NCE-1 date for Tecfidera®, and that it was imperative that Lachman file Pharmathen's ANDA for dimethyl fumarate on that date. Otherwise, Pharmathen would forever lose its opportunity to achieve first-filer status with respect to its ANDA, along with the lucrative exclusive generic drug marketing rights potentially available to first-filers under the Hatch-Waxman Act. Filing Pharmathen's ANDA on the NCE-1 date was not only critical in view of the company's forward-looking revenue stream for a generic version of Tecfidera®, it was necessary in order to justify the significant time and resources Pharmathen invested in evaluating the development of a generic version of the drug including the patents allegedly covering the drug and preparing its ANDA for dimethyl fumarate.

38. On December 21, 2016, Pharmathen wrote to Lachman "concerning the ANDA that we are planning for the end of March" and asked when Lachman would need the dossier from Pharmathen "in order to prepare it according to the FDA regulations and proceed with the submission on time?" That same day, Ms. Nataline replied on behalf of Lachman and asked "[d]oes Pharmathen want Lachman to review the ANDA for filing acceptance as well as prepare the ectd or just the latter," to which Pharmathen responded "*[w]e need both.*" Later that day, Ms. Nataline told Pharmathen that Lachman needed two weeks to compile, hyperlink and publish the ANDA.

39. On March 1, 2017, Pharmathen again stressed to Lachman and Ms. Nataline the importance of submitting Pharmathen's ANDA by the NCE-1 date of March 27, 2017.

40. On March 13, 2017-- two weeks prior to the NCE-1 date -- Pharmathen sent Lachman the finalized eCTD dossier to be submitted to the FDA in connection with Pharmathen's ANDA for dimethyl fumarate. Ms. Nataline promptly confirmed receipt of the dossier that same day, stating that Lachman had successfully "downloaded the documents."

41. On March 21, 2017, Pharmathen informed Lachman that "[i]f any additional data or amendments are needed for the dossier [they] will have to be prepared today in order to be on time for submission." That same day, Ms. Nataline replied: "[W]e don't need anything further."

42. On March 27, 2017, Pharmathen sought assurances from Ms. Nataline numerous times that the ANDA would be filed on that day. In addition to acknowledging that Lachman had still not processed the ANDA for submission, Ms. Nataline for the first time informed Pharmathen on the afternoon of the March 27, 2017 that *Pharmathen* would need to complete and sign Form FDA 356h required to submit the ANDA, even though Lachman had agreed to act as Pharmathen's agent for precisely this purpose, and despite the fact that Ms. Nataline informed Pharmathen just four days prior that Lachman would sign the form as Pharmathen's "Agent." Form 356h is the Application to Market a New or Abbreviated Drug or Biologic for Human Use that must accompany each ANDA that is filed with the FDA. In light of the time difference, Pharmathen received this request from Ms. Nataline at 12:45 a.m., a time at which no one from Pharmathen was available to complete and sign the form. Ms. Nataline claimed: "Our legal group will not let us sign as the applicant's responsible official. Sorry – for the last minute fire drill – we were able to do this in the past."

43. Lachman ultimately signed Form 356h on behalf of Pharmathen. However and notwithstanding the fact that (i) Lachman understood that Pharmathen was a first-time ANDA

filer, (ii) Lachman specifically agreed to "review the ANDA for filing acceptance and prepare the ectd," (iii) Pharmathen sent Lachman the final ectd dossier *two weeks before* the NCE-1 date as requested by Lachman, and (iv) Ms. Nataline told Pharmathen six days before the NCE-1 date that "we don't need anything further," Lachman failed to file Pharmathen's ANDA with the FDA on the NCE-1 date of March 27, 2017, and instead filed it on March 28, 2017.

44. The FDA regularly publishes a list of drug products for which an ANDA has been received including the date on which the first substantially complete generic drug application(s) was submitted to the agency that contained a Paragraph IV Certification. The identified date with respect to when the first substantially complete application(s) was submitted for Tecfidera® is March 27, 2017 (https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf).

45. Upon information and belief, several other generic pharmaceutical companies filed an ANDA with a Paragraph IV Certification on the NCE-1 date of March 27, 2017, and have received notice from the FDA that their filings were accepted. As a result, it is Pharmathen's competitors, and not Pharmathen, who achieved first-filer status in connection with their ANDA filings seeking approval to manufacture and market a generic version of Tecfidera®. Accordingly, it is Pharmathen's competitors, and not Pharmathen, who are now eligible to obtain a 180-day period of marketing exclusivity for their generic versions of Tecfidera® provided by the Hatch-Waxman Act.

46. Ms. Nataline claimed that Lachman missed the NCE-1 date because Pharmathen's documents were purportedly not "submission ready," and the two-week review period Lachman previously cited as sufficient for preparing an ectd only applied to "submission ready"

documents. Putting aside that the Consulting Agreement did not require Pharmathen to provide "submission ready" documents to Lachman, such a claim is belied by the fact that, as noted earlier, Ms. Nataline specifically stated that Lachman only needed two weeks to "review the ANDA for filing acceptance and prepare the ectd." Moreover, Lachman never raised any issue about such documents not being "submission ready" until after it missed the March 27, 2017 NCE-1 date. Further, any purported deficiencies in the formatting of documents Pharmathen sent to Lachman to submit as part of the ANDA should have been discovered well before the NCE-1 filing date for the ANDA. Upon information and belief, it appears as though Lachman did not even evaluate Pharmathen's ANDA to identify deficiencies or determine if it was "submission ready" until the day the ANDA was due to be filed. In any event, Ms. Nataline admitted that Lachman "did not foresee all the work that was required to upgrade the Pharmathen documents and it ultimately caused us to run out of time," and "apologize[d] for not managing expectations better."

47. Timely filing of Pharmathen's ANDA on the NCE-1 date was absolutely essential because, as Lachman knew full well, it would potentially accord a "first-filer" status to Pharmathen under the Hatch-Waxman Act. As such, Pharmathen would be eligible to receive the 180-day marketing exclusivity period over other generic pharmaceutical companies who filed their ANDAs for dimethyl fumarate *after* the NCE-1 date. As stated above, Tecfidera® is a drug for the treatment of relapsing multiple sclerosis with forecasted sales around or in excess of $4 billion per year in the near term. Upon information and belief, Lachman's failure to timely submit Pharmathen's ANDA for dimethyl fumarate on the NCE-1 date of March 27, 2017, as required by the Consulting Agreement inclusive of the various addendums thereto, has caused Pharmathen to lose tens if not hundreds of millions of dollars in revenue it otherwise would have earned through the sale of its generic version of Tecfidera® during the 180-day marketing

exclusivity period that Pharmathen would have been eligible to receive but for Lachman's failure to timely submit Pharmathen's ANDA. Indeed, Pharmathen's decision to pursue development of a generic version of Tecfidera® and the preparation of its ANDA for dimethyl fumarate was based on the assumption that the ANDA would be filed on the NCE-1 date in order to secure first-filer status to Pharmathen.

48. Lachman's failure to timely file Pharmathen's ANDA as agreed has caused further damage to Pharmathen in the form of research and development costs and legal fees incurred by Pharmathen in the development of its intended generic version of Tecfidera® and the preparation of its ANDA, including evaluation of the legal basis for invalidity and non-infringement with respect to patents that could cover the drug or method of using the drug including specifically those patents that are the subject of its Paragraph IV Certification. Pharmathen undertook those efforts and incurred those costs with the intent and understanding that its ANDA for dimethyl fumarate would be filed by the NCE-1 date for Tecfidera®, and Pharmathen would thereby achieve "first-filer" status under the Hatch-Waxman Act and the concomitant eligibility for generic marketing exclusivity. Through its conduct, Lachman deprived Pharmathen of the benefit of the research and development costs and legal fees it incurred in connection with its evaluation and preparation of an ANDA for dimethyl fumarate.

49. Pharmathen has incurred further damage in the form of the fees it paid to Lachman to assist with the preparation of Pharmathen's ANDA for dimethyl fumarate and to timely file the ANDA on the NCE-1 date of March 27, 2017.

50. Lachman's acts and omissions have further damaged Pharmathen's reputation in the generic pharmaceutical industry. Based on Lachman's assurances that it would file Pharmathen's ANDA for dimethyl fumarate on the NCE-1 date, Pharmathen represented to various third parties that it expected to achieve first-filer status for a generic version of

Tecfidera®. By and through its conduct, Lachman prevented Pharmathen from achieving its stated intention and cast a cloud over Pharmathen's reputation for generic drug development.

51. Both Pharmathen and the interests of its majority shareholder, BC Partners, who acquired its interest in Pharmathen in or about June 2015, have been affected significantly by Lachman's acts and omissions. Lachman's acts and omissions have also damaged Pharmathen's relationship with BC Partners. Upon information and belief, BC Partners acquired a majority interest in Pharmathen in order to invest in new product development, international expansion and attractive acquisitions in the growing generic pharmaceutical sector. For its part, Pharmathen expected that its partnering with BC Partners would enable the company to enhance its position in the global pharmaceutical market. By and through its conduct that prevented Pharmathen from achieving first-filer status in connection with its ANDA for dimethyl fumarate, Lachman has negatively impacted Pharmathen's relationship with its majority shareholder. Further, all shareholders of Pharmathen have been negatively impacted by the negative financial consequences resulting from Lachman's failure to file Pharmathen's ANDA on the NCE-1 date.

52. Lachman's conduct and actions described herein were at all times undertaken with reckless disregard for, or reckless indifference to, Lachman's contractual responsibilities and obligations and the rights of Pharmathen.

FIRST CAUSE OF ACTION
(Breach of Contract – Damages)

53. Plaintiff repeats and re-alleges each and every fact set forth in paragraphs 1- 52.

54. The Consulting Agreement inclusive of the addendums thereto, constitute a binding and valid contract entered into between Pharmathen and Lachman.

55. Pharmathen has performed all of its obligations under the Consulting Agreement.

56. Lachman breached its obligations under the Consulting Agreement by failing to timely file Pharmathen's ANDA with the FDA on the NCE-1 date for Tecfidera® as required.

57. Pharmathen is entitled to all damages resulting and flowing from Lachman's breach of the Consulting Agreement including, but not limited to: (1) the amounts Pharmathen paid to Lachman under the Consulting Agreement; (2) the revenues Pharmathen likely would have earned had Lachman filed Pharmathen's ANDA for dimethyl fumarate on the NCE-1 date of March 27, 2017, as required; and (3) research and development costs and legal fees incurred by Pharmathen, including costs and fees associated with the evaluation of a generic version of Tecfidera® and the preparation of Pharmathen's ANDA for dimethyl fumarate.

SECOND CAUSE OF ACTION
(Gross Negligence – Damages)

58. Plaintiff repeats and re-alleges each and every fact as set forth in paragraphs 1-57.

59. A relationship was established between Lachman and Pharmathen, which imposed an independent duty of care on Lachman owed to Pharmathen. Lachman breached the applicable standard of care associated with that relationship by acting with reckless indifference to and/or disregard of its responsibilities and obligations and Pharmathen's rights by failing to file Pharmathen's ANDA for dimethyl fumarate on the NCE-1 date of March 27, 2017.

60. Lachman breached the applicable professional standard of care that a professional consultant would provide in similar circumstances, in reckless indifference to and/or disregard of its responsibilities and obligations and Pharmathen's rights by failing to file the ANDA on the NCE-1 date of March 27, 2017.

61. As the direct and proximate result of Lachman's gross negligence, Pharmathen has suffered losses and will continue to suffer losses on account of Lachman's actions including, but not limited to: (1) the revenues Pharmathen would have likely earned had Lachman filed Pharmathen's ANDA for dimethyl fumarate on the NCE-1 date of March 27, 2017, as required; and (2) research and development costs and legal fees incurred by Pharmathen, including costs

and fees associated with the evaluation of a generic version of Tecfidera® and the preparation of Pharmathen's ANDA for dimethyl fumarate.

THIRD CAUSE OF ACTION
(Negligent Performance of Services – Damages)

62. Plaintiff repeats and re-alleges each and every fact as set forth in paragraphs 1-61.

63. A relationship was established between Lachman, as an expert consultant, and Pharmathen, as Lachman's client, which imposed on Lachman an independent duty of care owed to Pharmathen. Lachman breached its duty of care owed to Pharmathen by failing to file Pharmathen's ANDA for dimethyl fumarate on the NCE-1 date of March 27, 2017.

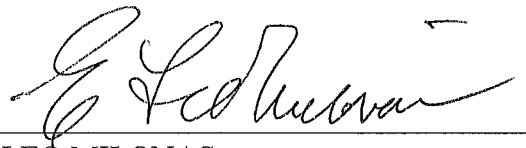
64. As the direct and proximate result of Lachman's breach of its duty of care owed to Pharmathen, Pharmathen has suffered losses and will continue to suffer losses on account of Lachman's acts and omissions including, but not limited to: (1) the revenues Pharmathen would have likely earned had Lachman filed Pharmathen's ANDA for dimethyl fumarate on the NCE-1 date of March 27, 2017, as required; and (2) research and development costs and legal fees incurred by Pharmathen, including costs and fees associated with the evaluation of a generic version of Tecfidera® and the preparation of Pharmathen's ANDA for dimethyl fumarate.

RELIEF SOUGHT

WHEREFORE, plaintiff hereby demands damages in an amount to be determined at trial, together with attorneys' fees and such other further relief as the Court deems just and proper.

Dated: November 21, 2017
New York, New York

PILLSBURY WINTHROP SHAW PITTMAN LLP

By: 

E. LEO MILONAS
EDWARD FLANDERS
1540 Broadway
New York, NY 10036
eleo.milonas@pillsburylaw.com
edward.flanders@pillsburylaw.com
(212) 858-1000

H. KEETO SABHARWAL
CEDRIC C.Y. TAN (*pro hac vice* forthcoming)
1200 Seventeenth Street, NW
Washington, DC 20036
keeto.sabharwal@pillsburylaw.com
cedric.tan@pillsburylaw.com
(202) 663-8000

MICHELLE A. HERRERA (*pro hac vice* forthcoming)
501 W. Broadway, Suite 1100
San Diego, CA 92101
michelle.herrera@pillsburylaw.com
(619) 234-5000

Attorneys for Plaintiff
PHARMATHEN, S.A.